

REMARKS

A. Rejection of Claims 43-53 - 35 U.S.C. §101

In the Office Action, Claims 43-53 were rejected under 35 U.S.C. §101 as directed to non-statutory subject matter.

While two prior Preliminary Amendments were submitted in this patent application, it is believed that Claim 54 currently remains in this patent application. Indeed, this patent application was published under Publication No. US 2003/0078808 A1 on April 24, 2003, including Claim 54. However, the present Office Action is directed to Claims 8-53, with no reference to Claim 54. For purposes of this Amendment, it will be assumed that Claim 54 would have been rejected for similar reasons as set forth in the Office Action for the related method claims.

Independent Claim 43 has been amended to recite that the method takes place in a system that includes a blood component collection instrument, a system computer and an interface operably connected to the system computer. The system database recited in Claim 43 is accessible by the system computer. Clearly, Claim 43, as amended, and Claims 44-54, as dependent upon Claim 43, are within the

technological arts.

Reconsideration and removal of the Section 101 rejection of Claims 43-54 are respectfully solicited.

B. Rejection of Claims 8-53 - 35 U.S.C. §102(e)

In the Office Action, Claims 8-53 [sic: 8-54] were rejected under 35 U.S.C. §102(e) as anticipated by Fletcher-Haynes et al. U.S. Published Application No. US 2001/0034614 A1 (hereinafter "Fletcher-Haynes").

Fletcher-Haynes does not fairly teach or suggest the invention claimed in Claims 8-54 for the following reasons.

Fletcher-Haynes is generally concerned with manipulating and optimizing blood collection procedures to maximize the type or amount of blood components that may be collected from a particular donor. As explained in paragraph 0162, these blood product components include platelets, plasma and RBCs. In certain paragraphs of Fletcher-Haynes, a disposable tubing set may be identified and recorded (Paragraph 0083), information may be supplied concerning the tubing set or bag used (including identifiers) for a particular blood component collection procedure (Paragraph 0125), or a final report may identify the tubing set that was used in a particular procedure (Paragraph 0166).

However, unlike the present invention, Fletcher-Haynes does not fairly disclose or teach a system database with an inventory of blood component collection soft goods (Claim 8), such as a blood component collection kit, a blood component collection solution, and a blood component collection transfer pack (Claim 10). Nor does Fletcher-Haynes teach a system computer with a quarantine field for indicating that at least a portion of the blood component collection soft goods is quarantined (Claim 8). Of course, blood component collection soft goods may need to be quarantined for any of a variety of reasons including that the soft goods have previously been opened and are therefore not sterile, that the soft goods are damaged, that the soft goods are past an end of use date, that the soft goods have been superceded by a newer part number, or the like. See, generally, Paragraphs 0132, 0134-0135, 0261, 0268-0269, 0392-0393 and FIGS. 72-75 of the present patent application. In short, Fletcher-Haynes is not concerned with quarantining of unsuitable soft goods.

The rejections of specific claims will now be considered in further detail:

Claim 8: As mentioned above, Fletcher-Haynes is not concerned with a system database with an inventory of blood component collection soft goods, nor with a system computer

with a quarantine field for indicating that at least a portion of the blood component collection soft goods is quarantined. While Paragraph 0195 of Fletcher-Haynes is cited as disclosing such an inventory, the inventory disclosed therein is of the blood components (also referred to as "units"), i.e., platelets, plasma and RBCs, that have previously been collected. Such units may be transferred between hospitals or collection centers. Similarly, cited Paragraph 0162 is concerned with the current collection status of such blood components, and has nothing to do with the quarantining of soft goods including an interface with a quarantine field for indicating the quarantine status, as claimed in Claim 8.

Claim 9: The cited Paragraphs 0083, 0125 and 0162 of Fletcher-Haynes have nothing to do with an identification of quarantined soft goods, as explained above.

Claims 10, 24, 33 and 45: The cited Paragraph 0315 of Fletcher-Haynes is an omnibus paragraph that seeks to expand upon the prior description of the invention contained therein. While mention is made of an "appropriate blood container (not shown)", nothing further is mentioned about soft goods. In particular, there is no disclosure that the soft goods may include a blood component collection kit, a blood component collection

solution, and a blood component collection transfer pack, as claimed in Claim 10. At most, Fletcher-Haynes teaches the use of a blood component collection kit.

Claims 23, 25-28, 39-42, 44 and 51-54: As presented above, Fletcher-Haynes does not fairly teach or disclose providing separate inventory data for each of the plurality of different types of soft goods, modifying such inventory data, generating a notification when the inventory is below a predetermined value, providing a reorder option for the soft goods, transmitting the reorder option to a remote access service for restocking, or communicating an identification of the quarantined soft goods to the system database.

Claim 31: As explained above in Claim 8, Fletcher-Haynes is does not fairly teach or suggest a system database with an inventory of blood component collection soft goods nor does Fletcher-Haynes fairly teach or suggest indicating that a portion of the soft goods inventory is quarantined. Thus, Fletcher-Haynes similarly does not teach a computer readable medium with a code segment that provides for accessing a system database with an inventory of blood component collection soft goods and a code segment that indicates that a portion of the soft goods inventory is quarantined, as claimed in Claim 31.

Claim 43: As explained above in Claim 8, Fletcher-Haynes is does not fairly teach or suggest a system database with an inventory of blood component collection soft goods nor indicating that a portion of the soft goods inventory is quarantined. Thus, Fletcher-Haynes similarly does not teach any methods for accessing a system database having an inventory of blood component collection soft goods and for indicating that a portion of the soft goods inventory is quarantined, as claimed in Claim 43.

The Applicants are not in agreement with the reasons cited in many of the remaining rejections of other dependent claims that are not specifically addressed above. However, since independent Claims 8, 31 and 43 are believed to be patentable over the cited art, the remaining dependent claims should also be allowable as placing additional limitations on these independent claims.

Reconsideration and removal of the rejections of Claims 8-54 are respectfully solicited.

CONCLUSION

For the foregoing reasons, it is believed that Claims 8-54 patentably distinguish over the prior art and that these claims are in condition for allowance. Early allowance is respectfully solicited.

It is believed that no fees are due. However, if any fees are applicable, kindly charge any such fees to our deposit account number 50-1039.

The Examiner is invited to call the undersigned to further discuss any of these matters.

Respectfully submitted,

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